UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHLOMO SPAR, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. CELSION CORPORATION, MICHAEL H. TARDUGNO, JEFFREY W. CHURCH, and NICHOLAS BORYS Defendants.	Case No. 3:20-cv-15228-MAS-DEA **AMENDED CLASS ACTION COMPLAINT** JURY TRIAL DEMANDED

Lead Plaintiff Milan Taraba ("Plaintiff"), individually and on behalf of all other persons similarly situated, by and through his undersigned attorneys, alleges the following against Defendants Celsion Corporation ("Celsion" or "Company"), Michael H. Tardugno, Jeffrey W. Church, and Nicholas Borys, based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Celsion, analysts' reports

and advisories about the Company, and information readily available from public sources. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Celsion securities between April 15, 2020 and July 13, 2020, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Throughout the Class Period, Defendants repeatedly and positively characterized pending results from a critical Phase III clinical trial. By opining that interim results would track former positive results and boasting that the Company was drafting communications with the FDA describing the trial's success, Defendants caused the price of Celsion common stock to more than triple on relatively enormous volume. In turn, Defendants caused the Company to sell approximately 2.67 million shares of Celsion common stock at the artificially inflated price of $3.75 per share for proceeds of over $9 million in cash to fund further development and trial of Celsion's potential drugs and therapies.

3. At the time they issued positive opinions about the blinded Phase III clinical trial, however, the interim results were fixed, an immutable data set. The then-existing data set did not simply "cut the other way" from Defendants' opinions. Rather, the interim data that was fixed as of April 2020 wholly undermined prior results, leading the independent Data Monitoring Committee ("DMC") to recommend that Celsion terminate the trial. Thus, at the time Defendants were severely recklessly pumping the price of Celsion common stock, an immutable interim data set existed that wholly undercut each and every one of their optimistic opinions.

4. In 2014 Celsion began its worldwide double-blind clinical trial, called OPTIMA, to test its lead product candidate, ThermoDox, a heat-activated treatment for primary liver cancer, along with at least 45 minutes of radiofrequency ablation. Celsion was, and remains, a development stage drug company with no approved, commercialized product. The Company developed the trial to assess whether the combination, rather than radiofrequency ablation alone, would significantly increase Overall Survival rates, the primary endpoint of the OPTIMA trial.

5. From 2014 to the start of the Class Period, Defendants repeatedly boasted that a post-hoc statistical analysis of a subgroup of patients from the Company's earlier HEAT study showed that ThermoDox combined with at least 45 minutes of radiofrequency ablation could increase Overall Survival ("OS"). To

analyze the trial's results at interim periods without unblinding the trial, Celsion established the DMC. In November 2019, analyzing the first interim data set from OPTIMA—after 128 trial participants had died—the DMC determined that the OPTIMA study should continue. Defendants repeatedly bragged to investors that this news was positive.

6. In April 2020, the Company announced that 158 trial participants had died, triggering the DMC's second interim analysis. From April 2020 through the end of the Class Period, Defendants not only repeatedly told investors they expected the results of the second interim analysis to be positive, but repeatedly told investors that the results could convince the FDA to accept Celsion's application to approve ThermoDox without even conducting the DMC's final analysis, at 197 deaths, and that they were already writing the application to the FDA.

7. What investors never learned during the Class Period is that Defendants' statements were materially misleading, the exact opposite of the disastrous interim data set. Objective facts existed at the time Defendants spoke that rendered all their statements false. Evaluating the 30 deaths that triggered the second interim analysis, the DMC concluded that the vast majority of deaths of trial participants, including 15 out of 16 in China and other Asian countries, by far the largest potential market for ThermoDox, had occurred in subjects who were receiving ThermoDox, and not the placebo. Directly contrary to Defendants'

statements of overwhelming optimism—including that they could achieve approval even without concluding OPTIMA—the existing data showed that OPTIMA could and would not achieve its primary endpoint or even muster results sufficient to continue the trial.

8. Defendants' statements caused Celsion's stock price to increase substantially, first in May 2020, and then in June 2020. Defendants took advantage of Celsion's artificially inflated stock price to raise funds from investors by selling its shares at $3.75 per share, when just 4 months earlier Celsion had raised funds at $1.05 per share.

9. On July 13, 2020, the end of the Class Period, Celsion announced that the DMC's second interim analysis showed that continuing the OPTIMA trial was futile. ThermoDox had failed to significantly increase Overall Survival rates. The OPTIMA trial was over. On this news, Celsion's stock price fell $2.29 per share, or 63.97%, to close at $1.29 per share on July 13, 2020.

10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Celsion is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

15. Plaintiff Milan Taraba purchased Celsion securities during the Class Period as stated in his Certification (ECF No. 8-5) and Loss Chart (ECF No. 8-6) Mr. Taraba purchased 10,000 shares of Celsion stock on June 26, 2020 at $4.15 per share. Mr. Taraba suffered losses as a direct and proximate result of Defendants' wrongful conduct.

16. Defendant Celsion is a Delaware corporation with principal executive offices located at 997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648. Celsion securities trade in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the symbol "CLSN."

17. Defendant Michael H. Tardugno ("Tardugno") has served as Celsion's Chief Executive Officer and President since January 3, 2007. He has been a member of the Board of Directors since January of 2007, and its Chairman since October of 2014.

18. Defendant Jeffrey W. Church ("Church") served as Celsion's Chief Financial Officer from July of 2010 to July of 2011, and since he was reappointed in July of 2013. He is a Celsion Executive Vice President.

19. Defendant Nicholas Borys ("Borys") has served as Celsion's Chief Medical Officer since October of 2007, and serves as Executive Vice President. He manages Celsion's clinical development and regulatory programs.

20. Defendants Tardugno, Church, and Borys are sometimes referred to herein as the "Individual Defendants."

21. The Individual Defendants and Celsion are referred to herein, collectively, as the "Defendants."

22. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating some or all of the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified false and misleading statements in violation of the federal securities laws.

23. Defendants Tardugno and Church signed SOX certifications attached to the May 15, 2020 10-Q reporting Celsion's results for the first quarter of 2020. In the SOX Certifications both Tardugno and Church certified that:

> 1. I have reviewed this Quarterly Report on Form 10-Q of Celsion Corporation;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements

> made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

24. Celsion is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

25. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

SUBSTANTIVE ALLEGATIONS

Background

26. In 1982 Augustine Cheung founded Cheung Laboratories, Inc, headquartered in Lawrenceville, New Jersey. In 2006 Cheung resigned and bought Cheung Laboratories' Canadian subsidiary, Celsion. Celsion states that it is a fully integrated,[1] clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual

[1] A "fully integrated" biotech company is active at all points of the value chain: research, development, manufacturing, and marketing/sales. A "partially integrated" firm exists at only some of the points in the value chain, *e.g.*, it may outsource development or out-license their product.

commercialization, for the treatment of cancer. Celsion has never received FDA approval for or commercialized any product it developed.

27. During the Class Period the Company's lead development product was ThermoDox, a proposed treatment for primary liver cancer or Hepatocellular Carcinoma ("HCC"). Defendants described ThermoDox as a proprietary, heat-activated liposomal encapsulation of doxorubicin to treat HCC. To treat patients, providers administered ThermoDox along with radiofrequency ablation ("RFA"). RFA is an electrical current produced by a radio wave that heats up a small portion of nerve tissue to destroy cancer cells. The Company stated that ThermoDox was designed to utilize the ability of RFA devices to ablate the center of the tumor while simultaneously thermally activating ThermoDox liposome to release its encapsulated doxorubicin directly to those cancer cells that survive RFA while potentially reducing drug exposure distant to the tumor site. According to Celsion, there are approximately 750,000-850,000 cases of HCC diagnosed each year, with half of the new diagnoses in China.

28. According to Celsion's 2020 10-K, Celsion has never had revenue from developed products, and has incurred significant net losses in each year since its inception, with cumulative net losses of $312 million as of December 31, 2020. The Company, therefore, has always needed to raise significant revenue to fund its future operations and clinical trials, which it attempted to do from the sale of equity, from

credit facilities, and from licensing and technology development agreements. According to Celsion, a failure to raise sufficient funds could force the Company to delay, reduce the scope of, or terminate research, development, and clinical programs.

The HEAT Clinical Trial

29. In 2013 Celsion concluded its HEAT clinical trial, a Phase III blinded clinical trial administering ThermoDox along with RFA, with the RFA administered for various lengths of time in both the treatment and placebo groups. The HEAT trial had 701 patients. The primary endpoint[2] of the HEAT study was improvement in progression-free survival ("PFS"). On January 31, 2013, Celsion announced that the HEAT study had failed to meet its primary endpoint.

30. Together with the National Institutes of Health ("NIH"), Celsion performed a post-hoc statistical analysis, concluding that 285 patients in a subgroup of the HEAT clinical trial who received both ThermoDox and at least 45 minutes of RFA ("subgroup") had a significantly better Overall Survival ("OS") rate than those receiving only RFA.

[2] The primary endpoint is the "main result that is measured at the end of a study to see if a given treatment worked (e.g., the number of deaths or the difference in survival between the treatment group and the control group). What the primary endpoint will be is decided before the study begins."
https://www.cancer.gov/publications/dictionaries/cancer-terms/def/primary-endpoint

31. Celsion continued to follow the patients in this subgroup to evaluate OS rates even after the HEAT study failed to meet its primary endpoint. On January 28, 2014, Celsion announced that those in the subgroup had a 55% improvement in OS, and a "hazard ratio" of 0.64. The hazard ratio compares the hazard of death to the treated group vs. the placebo group. A hazard ratio of 1 means a lack of association, a hazard ratio greater than 1 suggests an increased risk, and a hazard ratio below 1 suggests a smaller risk. A hazard ratio of 0.64 means that the treatment reduced the hazard of death by 36%. The hazard ratio for those receiving less than 45 minutes of RFA along with ThermoDox was 1.12, indicating that these patients had an increased risk of death. Celsion concluded that the results supported conducting another Phase III trial, in which all participants would receive ThermoDox and at least 45 minutes of RFA.

32. On August 6, 2015 Celsion announced that the HEAT study subgroup now had a 58% improvement in OS compared to those who received RFA alone, with a hazard ratio of 0.64. Celsion eventually announced that post-hoc statistical analysis of the subgroup found they lived 7.5 years versus 5.5 years for those who received RFA alone.

The OPTIMA Clinical Trial

33. In February 2014 Celsion announced that the U.S. Food and Drug Administration ("FDA") had approved its OPTIMA clinical trial, the Company's

planned pivotal, double-blind, placebo-controlled Phase III ThermoDox trial, in combination with at least 45 minutes of RFA, for treatment of single-lesion primary liver cancer.

34. The primary endpoint of the OPTIMA trial was increased Overall Survival. Celsion established an independent Data Monitoring Committee ("DMC") to analyze and report trial results to Celsion, to issue interim and final efficacy analyses, and to recommend whether to continue the clinical trial. The DMC would transmit its first interim report to Celsion after 128 deaths, and its second interim report after 158 deaths. The trial was to be concluded and a final report issued after 197 deaths.

35. The OPTIMA trial enrolled 556 patients at approximately 65 clinical sites. The patients were in at least 13 separate countries, with 5 of those countries in the Asia-Pacific region. China and Vietnam accounted for 37% of the total enrollees, with the largest number of patients in China. Enrollment in China and Vietnam began approximately 12 months after enrollment in the Unites States and Europe. The study was fully enrolled in August 2018.

36. Throughout the OPTIMA clinical trial Defendants expressed optimism about its successful progression, safety, and efficacy, even without results to support their optimism and confidence. During a November 7, 2015 quarterly conference call with analysts and investors to discuss the third quarter 2015 results, Defendant

Tardugno stated that "[t]he message from the medical community could not be clearer, the OPTIMA Study based on convincing timings from the OS subgroup that we've been following, has the potential to be the best and perhaps the only new opportunity for HCC patients in the foreseeable future."

37. During a May 16, 2016 quarterly conference call with analysts and investors to discuss the first quarter 2016 results, Defendant Tardugno stated, with respect to a trial that had delivered no results, that "[w]e are pleased with the progress we have seen in the OPTIMA trial[.]" On July 11, 2016 in a press release highlighting its participation in the Asia-Pacific Liver Cancer Expert Meeting, Tardugno stated that "the strength of the preclinical and clinical data reinforces our confidence in the potential of ThermoDox in HCC and for a successful trial outcome. We are extremely encouraged with the investigators' interest and enthusiasm with our approach."

38. An August 15, 2016 press release entitled "Celsion Corporation Reports Second Quarter 2016 Financial Results and Provides Business Update," quoted Defendant Tardugno stating that "data presentations and publications in multiple peer-reviewed forums continue to highlight the potential for a curative approach of ThermoDox plus optimized RFA."

39. In a November 10, 2016 press release entitled "Celsion Corporation Reports Third Quarter 2016 Financial Results and Provides Business Update,"

Tardugno touted the NIH post-hoc analysis of the HEAT study subgroup as indicating "mounting support for the OPTIMA study." The next day, during a November 11, 2016 earnings call to discuss third quarter 2016 results, Tardugno stated that "data supporting the OPTIMA study [is] stronger … now for over four years, no matter whether conducted by Celsion or independently scrutinized."

40. Success of the OPTIMA study in its Chinese cohort, the largest cohort in the OPTIMA study, was of vital importance to Celsion. In a December 16, 2016 press release, Celsion announced that the Chinese FDA ("CFDA") had told Celsion that if the ongoing OPTIMA study were successful, Celsion could file for ThermoDox approval with the CFDA, bypassing Chinese regulations requiring a foreign company to receive approval in the United States or European Union before it could file for approval with the CFDA. In a December 16, 2016 press release, Defendants called the data from the Chinese cohort of the HEAT trial, which had failed its primary endpoint, "remarkable."

41. In a March 16, 2017 press release entitled "Celsion Corporation Reports Year End 2016 Financial Results and Provides Business Update," Defendants touted the "superb execution" of their "ground-breaking" OPTIMA trial. Celsion repeated the "ground-breaking claim in its May 12, 2017 press release entitled "Celsion Corporation Reports First Quarter 2017 Financial Results and Provides Business Update."

42. Leveraging Celsion's association with the NIH, Defendants predicted that OPTIMA would succeed in increasing OS. During a May 12, 2017 quarterly conference call with analysts and investors, Tardugno bragged that "we believe our many analyses that support the OPTIMA study, or if you have any confidence in the independent opinion of the National Institutes of Health, then you should have to agree that ***the chance of success with our OPTIMA study is as good as it gets in our industry***."

43. Defendants repeatedly tied the post-hoc subgroup analysis from the HEAT study to expected success in the OPTIMA clinical trial. In a September 27, 2017 press release, the Company bragged that "investigators fully recognize the value of the findings from the HEAT Study."

44. During a November 14, 2017 earnings conference call to discuss the results for the third quarter of 2017, discussing the OPTIMA study, Defendant Tardugno argued that the "hypothesis [for the success of the OPTIMA trial] is supported with some of the most persuasive and productive prospective and retrospective data that has ever been taken in my experience for a clinical trial."

45. Defendants repeatedly put a positive spin on the expected success of the OPTIMA trial, even as they had no actual results. On August 14, 2018, during a quarterly conference call with analysts and investors to discuss the second quarter 2018 results, Tardugno stated that "the evidence supporting the thesis for the

OPTIMA study is overwhelming" and that if successful ThermoDox would be "one of the most important new drugs in oncology in a generation, if not our lifetime. I believe that sincerely."

46. In an August 5, 2019 press release entitled "Celsion Announces Data Lock for First Interim Analysis in OPTIMA Phase III Study of ThermoDox in Primary Liver Cancer," Celsion announced that the prescribed 128 deaths had been reached for the DMC's first interim analysis.

47. Again citing the HEAT study subgroup statistical analysis to convey the expected success of the OPTIMA clinical trial, during an August 15, 2019 quarterly conference call with analysts and investors, Tardugno boasted that the results of the HEAT study subgroup were "nothing short of remarkable." Further, on August 27, 2019, Celsion issued a press release entitled "Celsion Announces Publication of findings from Single-Site Study in China of ThermoDox Plus RFA in the Journal of Cancer Research and Therapeutics." The article was authored by, among others, Celsion's Principal Investigator in the OPTIMA Study. The press release boasted that a study of the HEAT study subgroup participants ***in a single test site in China*** showed increased OS for those receiving ThermoDox and at least 45 minutes of RFA. Celsion's press release did ***not*** reveal that, at most, only 11 trial participants at the single site received ThermoDox and RFA.[3]

[3] https://pubmed.ncbi.nlm.nih.gov/31436231/.

48. On November 1, 2019, the DMC met and performed its first interim analysis of the data after the first 128 deaths. On November 4, 2019, in a press release entitled "Celsion Reports Unanimous Independent Data Monitoring Committee Recommendation to Continue the Phase III OPTIMA Study of ThermoDox in Primary Liver Cancer," Celsion announced that having reached the first interim analysis point at 128 deaths (in August 2019), the DMC had analyzed results and recommended continuing the OPTIMA clinical trial. The press release noted that the next DMC interim analysis would be conducted after 158 deaths.

49. In the November 4, 2019 press release, Defendant Tardugno stated that the DMC drew no conclusions about Overall Survival, the primary endpoint of the OPTIMA study, because the median time that OPTIMA trial participants had been followed was only 25 months, not long enough to draw conclusions about OS. The DMC's data review demonstrated that median PFS (which was ***not*** the OPTIMA study's primary endpoint) as of August 2019 was 17 months, almost identical to the HEAT study subgroup results.

50. On November 14, 2019, in a press release entitled "Celsion Corporation Reports Third Quarter 2019 Financial Results and Provides Business Update," the Company stated that the DMC's analysis demonstrated that "progression-free survival (PFS) and overall survival (OS) data appear to be tracking with patient data observed at a similar point in the" HEAT trial "upon which the OPTIMA Study is

based." In the November 14, 2019 10-Q reporting the results for the third quarter of 2019, the Company informed investors that at the next interim analysis, at 158 events (deaths), the hazard ratio for success would be 0.70.

51. The next day, November 15, 2019, during a quarterly conference call with analysts and investors to discuss the results for the third quarter of 2019, Defendant Tardugno stated that the DMC "found no evidence of futility or any safety issues of concern." Even as Defendant Tardugno admitted, however, that "we did not meet the required hazard ratio at the first interim analysis," he stated that "the science, the medical results, and the preclinical evidence are all compelling … even to the skeptic members of the Flat Earth Society."

52. Celsion's need to continue raising cash never abated. On March 3, 2020, Celsion published a letter from Defendant Tardugno to shareholders stating that on February 27, 2020, Celsion had entered into a Securities Purchase Agreement with four institutional investors, agreeing to sell almost 4.6 million shares for only $1.05 per share, grossing $4.8 million.

53. By March of 2020, data existed that would prevent the OPTIMA trial from achieving its primary endpoint and belied all of Defendants' optimistic statements. Between September 2019 and March 2020, during the period evaluated in the second interim analysis, there were 26 consecutive trial participant deaths, in a pattern significantly different than those that preceded the first interim analysis. Of

the 26 deaths, encompassing 87% of the deaths that occurred between the first and second interim analyses, 17 of the deaths, or 65%, were of patients who had received ThermoDox and not the placebo.

54. Further, between November 4, 2019 and April 27, 2020, the period evaluated in the second interim analysis, 16 deaths occurred in five Asia-Pacific countries, and 15 of those test subjects had been receiving ThermoDox and not the placebo.

55. Even as immutable facts existed dooming the OPTIMA trial to failure, Defendants persisted with optimistic statements about the expected result of the clinical trial. On April 15, 2020, the start of the Class Period, Celsion issued a press release entitled "Celsion Reports that Sufficient Events Have Been Reached for the Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox in Primary Liver Cancer."[4] Though the Company stated that no conclusion could be drawn concerning Median Overall Survival for the OPTIMA study as of August 2019, when the 128 deaths number had been reached, triggering the DMC's first interim analysis, Celsion nevertheless boasted that OS "appears to be consistent with the HEAT Study subgroup." Tardugno stated that Celsion was "quite optimistic for a positive outcome" from the second interim analysis. The Company announced that

[4] Celsion did not file this press release with the SEC on a Current Report on Form 8-K.

the hazard ratio for success for the second interim analysis was 0.70. Further, a successful study would have "blockbuster revenue potential."

56. In a May 15, 2020 10-Q reporting results for the first quarter of 2020, Celsion revealed that the OPTIMA study had reached the prescribed number of 158 deaths triggering the DMC's second interim analysis. The Company stated that the target hazard ratio for success was 0.70, a 30% reduction in the risk of death. In a press release the same day, the Company revealed that the P-value for the second interim analysis would be 0.022.[5]

57. With knowledge that OPTIMA had reached an inflection point, marked sadly by 158 deaths, but claiming not to know the ratio of deaths in those who had received ThermoDox versus those who had received a placebo, Defendants chose nevertheless to characterize the results with optimism. The same day, May 15, 2020, during a quarterly conference call with analysts and investors to discuss the first quarter 2020 results, Defendant Tardugno revealed the "exciting news" that the OPTIMA study had reached 158 deaths and so the DMC would conduct its next interim analysis. Tardugno expressed confidence in the "very good potential for success at this analysis," and that "the study is on track for success," based on feedback from "thought leaders of the medical community and distinguished

[5] The P-value measures the chance that a result will be duplicated in another test. A P-value of 0.02 means that the result would be expected to be the same in 98% of additional tests.

scientists." Tardugno stated that the hazard ratio and P-value targets for success compared favorably to those metrics observed in the HEAT study subgroup that received at least 45 minutes of RFA, which had a "two year overall survival advantage for patients treated with a single dose of ThermoDox," with a "remarkable median time to death of more than seven and a half years." Defendant Church told analysts that "Celsion is in excellent financial shape with sufficient capital to fund operations through the second quarter of 2021."

58. During that same May 15, 2020 quarterly conference call with analysts and investors, Defendant Tardugno told investors that at the second interim analysis the targets for success, the hazard ratio and P-value targets, would be lower than for the first interim analysis, and the targets for success even lower at the final analysis. Defendant Tardugno even stated that the results of the second interim analysis might be so positive that the FDA would not even require the OPTIMA study continue to the final analysis, twice describing the final analysis as only "if it's necessary." Tardugno continued that Celsion was already "drafting … the NDA and NAA for Europe for ThermoDox and HCC," continuing "for example, if we announced positive data from the second interim analysis in July, we would hope to have a filing made around the beginning, the very beginning of 2021." Later in the call, responding to an analyst's question, Defendant Tardugno again told investors that Celsion expected the results of the second interim analysis to be positive, stating that

if "tomorrow we were to have a positive result from the DMC, we would immediately place a call to the FDA [and tell them that we] would like to have a pre-NDA meeting with them … then we submit a formal letter to the FDA requesting that meeting, and we're drafting that letter as we speak."

59. Defendants' efforts characterizing the then-existing results of the second interim analysis positively succeeded in convincing analysts. Analyst Michael Cross of Jones Trading began his questioning of the Company at the May 15, 2020 quarterly conference call with analysts and investors by stating ""I'll start with OPTIMA given that it sounds like the next time we may be talking about this program that you may have a positive result here hopefully."

60. Following the April 15, 2020 and May 15, 2020 disclosures expressing optimism about the results of the second interim analysis and ThermoDox's "blockbuster revenue potential," Celsion's stock price and volume increased dramatically. On May 20, 2020, the stock price increased from $1.48 to $1.72 on volume of 3.6 million, almost ten times the previous day's volume. The price increased to $2.35 on May 21, 2020, on volume of 7.3 million. The price jumped again to $3.03 on May 22, 2020 on volume of 22.6 million shares.

61. As the date of the DMC's second interim analysis neared, Defendants continued to tout the expected positive results. On June 15, 2020, Celsion held its annual shareholder meeting. Addressing an audience representing owners of over 20

million Celsion shares, or 71% of the total shares, the Company continued priming investors for positive results from the DMC's second interim analysis. Defendant Tardugno, stating again that the threshold for success at the second interim analysis was lower than for the first interim analysis, and the threshold for success at the final analysis would be lower still, declared that "our confidence is quite good for a positive result at this meeting of the DMC." Tardugno further suggested, again, that the results of the second interim analysis would be so positive that no final analysis would be required before approaching the FDA, saying "if a final analysis is needed in less than 9 months from now." Later in the meeting, again discussing the final analysis, Tardugno stated "if it's needed."

62. Following the June 15, 2020 shareholders meeting expressing optimism about the results of the second interim analysis, Celsion's stock price and volume again increased dramatically. Between June 9, 2020 and June 19, 2020, the stock price rose from $2.77 to $5.26, on total volume of over 50.5 million shares, a price per share far higher than the $1.05 per share price paid by institutional investors on February 27, 2020.

63. All the while Defendants were opining on the likely success of the second interim analysis, in the face of then-existing results that showed the exact opposite, not only did their optimistic statements increase the price of CLSN stock materially, but on June 22, 2020 Celsion announced that it had used the artificially

inflated stock price to raise money at $3.75 per share, far higher than the late February 2020 raise at $1.05 per share.

False and Misleading Statements and Omissions

64. On April 15, 2020, the start of the Class Period, Celsion issued a press release entitled "Celsion Reports that Sufficient Events Have Been Reached for the Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox in Primary Liver Cancer." Though the Company stated that Median Overall Survival for the OPTIMA study had not been reached as of August 2019, so no conclusion could be drawn, it nevertheless told investors that it "appears to be consistent with the HEAT Study subgroup." Tardugno stated that Celsion was "***quite optimistic for a positive outcome***." The Company announced that the hazard ratio for success was 0.70.

65. The foregoing statements were materially false and/or misleading because information existed that directly contradicted Defendants' statement about a "positive outcome" and the steps they had begun to achieve FDA approval of ThermoDox. The contradictory information did not simply cut the other way. Rather, far from applying for FDA approval of ThermoDox early, based on the data set that existed before the Class Period, the DMC found that continuing OPTIMA was futile. Defendants were duty-bound either to disclose the contradictory information, or refrain from positively characterizing the OPTIMA results and the prospects for

FDA approval. Defendants were severely reckless in characterizing the OPTIMA results positively given then-existing information that:

(a) Out of 26 consecutive deaths that occurred between September of 2019 and March of 2020, 17 out of the 26 were of patients receiving ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study; and

(b) Between November 4, 2019 and April 27, 2020, 16 patient deaths occurred in Asia-Pacific countries, and 15 of those patients had received ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study.

66. Defendants continued touting the expected positive results of the second interim analysis despite existing historical information to the contrary. During a May 15, 2020 quarterly conference call with analysts and investors to discuss the first quarter 2020 results, Defendant Tardugno, discussing the second interim analysis, expressed confidence in the "***very good potential for success at this analysis***," and that "***the study is on track for success***," based on feedback from "thought leaders of the medical community and distinguished scientists." Tardugno stated that the hazard ratio and P-value targets for success compared favorably to

those metrics observed in the subgroup in the HEAT study that received at least 45 minutes of RFA, which had a "two year overall survival advantage for patients treated with a single dose of ThermoDox," with a "remarkable median time to death of more than seven and a half years."

67. During that same May 15, 2020 quarterly conference call with analysts and investors, Defendants disclosed actual steps they were taking in anticipation of results so positive from the second interim analysis that the final analysis might be cancelled. Defendant Tardugno told investors that at each interim analysis the bar for success, the hazard ratio and P-value targets, would be lower than the previous analysis, and even lower at the final analysis. Defendant Tardugno even stated that the results of the second interim analysis might be so positive that the FDA would not even require the OPTIMA study to continue to the final analysis, twice describing the final analysis as only "***if it's necessary***." Tardugno continued that Celsion was already "***drafting … the NDA and NAA for Europe for ThermoDox and HCC***," continuing "for example, if we announced positive data from the second interim analysis in July, we would hope to have a filing made around the beginning, the very beginning of 2021." Later in the call, responding to an analyst's question, Defendant Tardugno again told investors that Celsion expected the results of the second interim analysis to be positive, stating that if "tomorrow we were to have a positive result from the DMC, we would immediately place a call to the FDA [and

tell them that we] would like to have a pre-NDA meeting with them … then we submit a formal letter to the FDA requesting that meeting, ***and we're drafting that letter as we speak***."

68. The foregoing statements were materially false and/or misleading because information existed that directly contradicted Defendants' statement about a "very good potential for success" and that "the study is on track for success," and the steps they had begun to achieve FDA approval of ThermoDox. The contradictory information did not simply cut the other way. Rather, far from applying for FDA approval of ThermoDox early, based on the data set that existed before the Class Period, the DMC found that continuing OPTIMA was futile. Defendants were duty-bound either to disclose the contradictory information, or refrain from positively characterizing the OPTIMA results and the prospects for FDA approval. Defendants were severely reckless in characterizing the OPTIMA results positively given then-existing information that:

(a) Out of 26 consecutive deaths that occurred between September of 2019 and March of 2020, 17 out of the 26 were of patients receiving ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study; and

(b) Between November 4, 2019 and April 27, 2020, 16 patient deaths occurred in Asia-Pacific countries, and 15 of those patients had received ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study.

69. On June 15, 2020, Celsion held its annual shareholder meeting. Addressing an audience representing owners of 20 million shares of Celsion stock, 71% of the total shares, the Company continued priming investors for positive results from the DMC's second interim analysis and suggesting that the results would be so positive that no final analysis would be required. Defendant Tardugno stated that the threshold for success at the second interim analysis was lower than for the first interim analysis, and the threshold for success at the final analysis would be lower still, Defendant Tardugno stated that "***our confidence is quite good for a positive result at this meeting of the DMC***." Tardugno further suggested, again, that the results of the second interim analysis would be so positive that no final analysis would be required before approaching the FDA, saying "***if a final analysis is needed in less than 9 months from now***." Later in the meeting, again discussing the final analysis, Tardugno stated "***if it's needed***."

70. The foregoing statements were materially false and/or misleading because information existed that directly contradicted Defendants' statement about

a "confidence" about a "positive result at this meeting of the DMC," and the steps they had begun to achieve FDA approval of ThermoDox. The contradictory information did not simply cut the other way. Rather, far from applying for FDA approval of ThermoDox early, based on the data set that existed before the Class Period, the DMC found that continuing OPTIMA was futile. Defendants were duty-bound either to disclose the contradictory information, or refrain from positively characterizing the OPTIMA results and the prospects for FDA approval. Defendants were severely reckless in characterizing the OPTIMA results positively given then-existing information that:

(a) Out of 26 consecutive deaths that occurred between September of 2019 and March of 2020, 17 out of the 26 were of patients receiving ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study; and

(b) Between November 4, 2019 and April 27, 2020, 16 patient deaths occurred in Asia-Pacific countries, and 15 of those patients had received ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study.

71. On June 22, 2020, Celsion filed a Prospectus with the SEC concerning the sale of 2,666,6667 shares of Celsion stock through underwriter Oppenheimer & Co. In the prospectus Celsion not only provided a summary of the November 4, 2019 DMC recommendation, but expressed optimism about the upcoming results of the second interim analysis, writing "***this tracking appears to bode well for success at the next pre-planned interim efficacy analysis***."

72. The foregoing statements were materially false and/or misleading because information existed that directly contradicted Defendants' statement about "tracking appear[ing] to bode well for success," and the steps they had begun to achieve FDA approval of ThermoDox. The contradictory information did not simply cut the other way. Rather, far from applying for FDA approval of ThermoDox early, based on the data set that existed before the Class Period, the DMC found that continuing OPTIMA was futile. Defendants were duty-bound either to disclose the contradictory information, or refrain from positively characterizing the OPTIMA results and the prospects for FDA approval. Defendants were severely reckless in characterizing the OPTIMA results positively given then-existing information that:

(i) Out of 26 consecutive deaths that occurred between September of 2019 and March of 2020, 17 out of the 26 were of patients receiving ThermoDox and not the placebo, and those deaths

ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study; and

(ii) that between November 4, 2019 and April 27, 2020, 16 patient deaths occurred in Asia-Pacific countries, and 15 of those patients had received ThermoDox and not the placebo, and those deaths ensured that the DMC would find futility, jeopardizing the viability of continuing the OPTIMA Study.

The Truth Emerges

73. On July 13, 2020, during pre-market hours, Celsion filed a press release entitled "Celsion Corporation Receives Recommendation from Independent Data Monitoring Committee to Consider Stopping the Phase III OPTIMA Study." The Company stated that "it ha[d] received a recommendation from the independent [DMC] to consider stopping the global Phase III OPTIMA Study of ThermoDox in combination with [RFA] for the treatment of [HCC], or primary liver cancer." According to the Company, "[t]he recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020," which "found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903."[6] The DMC did not recommend Celsion stop

[6] The futility boundary is the hazard ratio at which the study is clearly not producing the desired result. A futility boundary of 0.90 means the treatment only reduced the risk of death by 10%.

(rather than consider stopping) the OPTIMA study because the P-value was 0.524, far in excess of the 0.022 goal, providing "uncertainty" as to whether the results would be repeated if identical tests would be performed. Celsion stated that it was "surprised and disappointed" at the OPTIMA study interim results, which it claimed it had "never … anticipated."

74. On this news, Celsion's stock price fell $2.29 per share, or 63.97%, to close at $1.29 per share on July 13, 2020.

75. In a conference call on July 15, 2020, Defendant Tardugno stated that the Company was now unblinded. He revealed that the hazard ratio for the first interim analysis, on November 4, 2019, had been 0.77. Discussing the second interim analysis period, Tardugno stated that "the last 25% of patients who died had a lesser treatment effect than the first 75%." He continued that "there is but a very slim chance that the study will meet its prespecified target for success." The Company did not stop the OPTIMA study.

76. In an August 4, 2020 press release entitled "Celsion Corporation to Continue Following Patients in Phase III OPTIMA Study for Overall Survival," Celsion announced that there had been 26 consecutive patient deaths that occurred between September 2019 and March 2020, represented in the DMC's second interim analysis, that "behave[d] far differently from the balance of the patients who have died as of this date." Celsion stated that "removing the 26 consecutive patient

deaths" from the pre-planned analysis suggests that "the OPTIMA Study OS pattern is similar to the prospective HEAT Study subgroup upon which the OPTIMA Study is based." The company concluded that these 26 deaths may point to a "data maturity issue." "Removing the 26 consecutive patients deaths" from the analysis, of course, means ignoring, and excluding, nearly every single death that occurred between the DMC's first and second interim analysis from the results.

77. In a press release filed on August 14, 2020 entitled "Celsion Corporation Reports Second Quarter 2020 Financial Results and Provides Business Update," Celsion again announced that it would continue the OPTIMA Study, with Defendant Tardugno describing the DMC recommendation as "wholly unexpected," adding that "this development had never been anticipated by the Company or our advisors, nor would it have been forecasted by the first pre-planned efficacy analysis." The Company stated that the decision to continue was made easier because the OPTIMA Study was fully enrolled, and the vast majority of trial expenses had already been incurred.

78. The Company's August 14, 2020 press release further quoted Tardugno stating that "blinded data available to the Company appeared to be tracking well against the sub-group analysis of the Company's earlier HEAT Study, upon which the OPTIMA Study is based." Further, the Company further stated that "the unexpected and marginally crossed futility boundary, suggested by the Kaplan-

Meier analysis at the second interim analysis, may be associated with a data maturity issue."[7]

79. During an August 14, 2020 quarterly conference call with analysts and investors to discuss the results of the second quarter of 2020, Defendant Tardugno referenced the 26 consecutive deaths the Company had disclosed on August 4, 2020. Tardugno stated that the "vast majority" of deaths were in the treatment arm and "more than doubled" the number of deaths in the control (placebo) arm, by 17 to 9. Tardugno further stated that the fact that OPTIMA study sites in China and Vietnam joined the study 12-18 months after the trial was initiated may demonstrate a potential "[data] maturity issue." Further, Tardugno stated that the 26 deaths "may be a regional issue," *i.e.*, where the trial participants were treated.

80. On October 12, 2020, Celsion issued a letter to shareholders from Defendant Tardugno updating the data analysis from the OPTIMA study and discussing other potential uses for ThermoDox. The Company revealed that between the first and second interim analyses, between November 4, 2019 and April 27, 2020, 16 deaths had occurred in five Asia-Pacific countries, ***and 15 of those test subjects***

[7] The Kaplan–Meier estimator is a non-parametric statistic used to estimate the survival function from lifetime data. In medical research, it is often used to measure the fraction of patients living for a certain amount of time after treatment. Maturity of survival data, *i.e.*, whether enough time has passed from treatment to allow a valid statistical analysis of Overall Survival, is a key consideration in the assessment of the value of oncology drugs based on clinical trial evidence.

had been receiving ThermoDox and not the placebo. Celsion announced that it had engaged a "global biometrics contract research organization with forensic statistical analysis capability" to determine whether there was a basis to continue following the OPTIMA study participants. Celsion also announced that it had submitted all of the trial data to the NIH for statistical analysis.

81. On February 11, 2021, Celsion issued a letter to shareholders from Defendant Tardugno stating that neither the NIH nor the "biometrics contract research organization," had found "any evidence or significance of factors that would justify continuing to follow patients for OS." Celsion thus informed all testing sites to discontinue following patients, ending the OPTIMA Study.

82. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER FACTS

83. Following the April 15, 2020 and May 15, 2020 disclosures expressing optimism about the results of the second interim analysis, ThermoDox's "blockbuster revenue potential," and suggesting that the results of the second interim analysis might be so positive that no final analysis would be required, Celsion's stock price and volume increased exponentially. On May 20, 2020, the stock price increased from $1.48 to $1.72 on volume of 3.6 million, almost three times the

previous day's volume. The price increased to $2.35 on May 21, 2020, on volume of 7.3 million. The price jumped again to $3.03 on May 22, 2020 on volume of 22.6 million shares.

84. Following the June 15, 2020 disclosures at the shareholder meeting expressing optimism about the results of the second interim analysis and suggesting that the results of the second interim analysis might be so positive that no final analysis would be required, Celsion's stock price and volume again increased exponentially. Between June 9, 2020 and June 19, 2020, the stock price rose from $2.77 to $5.26, on total volume of over 50.5 million shares.

85. Celsion took advantage of artificially elevating its stock price through positive statements that belied the actual facts by issuing stock, raising far more cash than would have been realized before April 15, 2020 or May 15, 2020.

86. On June 22, 2020, Celsion filed a Prospectus with the SEC announcing that it had sold 2,666,667 shares of Celsion common stock to the underwriter Oppenheimer & Co., at $3.75 per share, for the underwriter to sell to individual investors, raising a little over $10 million, and netting a little over $9.3 million.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

87. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Celsion securities during the Class Period (the

"Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

88. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Celsion securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Celsion or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

89. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

90. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and

securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

91. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether Defendants' acts as alleged violated the federal securities laws;
- whether Defendant' statements to the investing public during the Class Period misrepresented material facts about the business, operations, and management of Celsion;
- whether the Individual Defendants caused Celsion to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- whether the prices of Celsion's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

92. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it

impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

93. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- throughout the Class Period, the Company's securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Celsion securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and
- Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

94. Based upon the foregoing, the market for Celsion's securities promptly digested current information regarding Celsion from all publicly available sources and reflected such information in Celsion's stock price. Under these circumstances,

all purchasers of Celsion's securities during the Class Period suffered similar injury through their purchase of Celsion's securities at artificially inflated prices and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

95. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

NO SAFE HARBOR

96. Celsion's "Safe Harbor" warnings accompanying its reportedly forward-looking guidance statements issued during the Class Period were ineffective to shield whose statements from liability. There were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement

was authorized or approved by an executive officer of Celsion who knew that the statement was false when made.

97. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the non-forward-looking statements alleged as false in this Complaint. Those statements relate to then-existing facts and conditions.

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

98. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

99. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

100. During the Class Period, Celsion and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and omitted material facts.

101. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

102. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading and omitted material information; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements or material omissions, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein. Information showing that the Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Defendants' knowledge

and control. As the senior managers and/or directors of Celsion, the Individual Defendants had knowledge of the details of Celsion's internal affairs.

103. The Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

104. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or on the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Defendants' false and misleading statements and omissions.

105. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information

which Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

106. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

107. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

108. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

109. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of Celsion's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's financial position and business practices.

110. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to

correct promptly any public statements issued by Celsion which had become materially false or misleading.

111. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Celsion disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Celsion to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Celsion's securities.

112. Each of the Individual Defendants, therefore, acted as a controlling person of Celsion. By reason of their senior management positions and/or being directors of Celsion, each of the Individual Defendants had the power to direct the actions of, and exercised the same, to cause Celsion to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Celsion and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

113. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Celsion.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 27, 2021

Respectfully submitted,

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Attorneys for Lead Plaintiff and the Class

CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2021, I electronically filed the foregoing ***Amended Class Action Complaint*** with the Clerk of Court using the CM/ECF system, which will send notification of such to all CM/ECF participants.

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